

UTAH MEDICAL
PRODUCTS INC.



K960496

JUN 27 1996

SMDA 510(k) Summary

Trade Name: Liberty Lite System
Common Name: Electrical Pelvic Floor Stimulation System
Classification: Nonimplanted Electrical Continence Device. 21 CFR §876.5320.

The UMP Liberty Lite PFS System is a battery operated electrostimulation device with an intravaginal applicator that applies electrical stimulation through electrodes on the applicator, to help train neuromuscular tissue in the pelvic floor in order to improve or restore urinary continence in females. The patient uses the system once or twice per day at home. Each session lasts for 15 to 30 minutes without the need for active involvement of the patient or the physician.

Liberty Lite is substantially equivalent to the UMP Liberty System cleared for marketing under 510(k) K943250 and the Hollister InCare Applicator cleared for marketing under 510(k) K891773. Although the Liberty Lite Stimulator utilizes a simplified user interface, the stimulation output has equivalent waveforms. The Liberty Lite Applicator and the InCare Applicator have some differences in their physical construction and dimensions, however, they both utilize a single electrode pair with equivalent anatomical placement and active surface area. Liberty Lite is designed to be more cost effective and user friendly than currently marketed devices.

Materials used in the Liberty Lite Applicator that contact the vaginal tissues are equivalent to materials used in the InCare Applicator.


Kevin L. Cornwell
President & CEO